04-01-04

REMARKS

Examination of the present application is to be based on claims 30, 32-43, 45-54, 62, and 63-80.

The office action of October 6, 2003 and the art relied on by the Examiner have been carefully examined.

I. Amendments to the claims

Claims 30, 43, and 54 have been amended to recite: "the particulate matter selected from the group consisting of particulate matter of whole plants, leaves, roots, dried fruits and active pharmaceuticals". Support for the added feature can be found at page 5, lines 17-29.

Claims 30, 43, and 54 have been amended to recite "in substantial absence of fillers, diluents or binders" when "generating pellets." Support for the added feature can be found at page 3, lines 1-2 and page 5, lines 24-25.

Claims 35 and 46 have been amended to recite "by rotating inner roller means" instead of "by counter rotating roller means". Support for this wording can be found on page 3, lines 10-11 and on page 5, lines 3-5.

Claims 39 and 50 have been amended to recite "at at least about 95% of hydration" instead of "penetrated by at least about 95% hydration." Support for this wordings can be found on page 3 lines 4-6.

The Applicant submits that no new matter has been added.

II. New Claims

New claims 62-80 have been added. Support for these claims can be found on page 5, lines 17-29, on pages 8 and 9 table 1 and on page 2 lines 21-23. The Applicant submits that no new matter has been added.

III. Specification

In the Action, the Examiner requests the disposition of the parent application to be noted in the specification. The Applicant has complied with this request by inserting a "CROSS REFERENCE TO RELATED APPLICATIONS" at the beginning of the specification.

IV. Claim Rejections - 35 USC §112

In the Action, the Examiner rejects claims 54-61 under 35 USC 112, second paragraph. The Applicant has amended claim by canceling the terms "preventing" and "standard." Further, the Applicant has amended claims 55-61 to put them in a proper independent form. Therefore, the Applicant submits that the clarity rejections have been overcome.

V. Claim Objections

In the Action, the Examiner objects to claims 55-61 under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Applicant has amended claims 55-61, to put them in a proper independent form. Therefore, the Applicant submits that the clarity objections have been overcome.

VI. Claims rejections - 35 USC § 102

In the Action, the Examiner rejects claims 30, 31, 33, 37, 41-44, 48, 52, 55-57, and 59 under 35 USC § 102(b) as being anticipated by U.S. Pat. 4,072,535 to Short et al. The Applicant respectfully disagrees and submits that the above claims are not anticipated by Short for the reasons that follow.

1.

Claim 30 recites: "directing a particulate matter into a pellet mill ... the particulate matter selected from the group consisting of particulate matter of whole plants, leaves, roots, dried fruits and active pharmaceuticals..." (Emphasis added).

Short describes "compacting starting starch raw material" (Short column 11 lines 67-68) where "the starting starch suitably may be any ... starch derived from the root, stem or fruit of a plant" (Short column 10 lines 62-64). We submit that "starch derived from the root, stem or fruit of a plant" (Short column 10 lines 62-64) is not "particulate matter of ... roots", "particulate

2.

3.

matter of ... dried fruits", or "particulate matter of whole plants". Also "starch derived from the root, stem or fruit of a plant" (Short column 10 lines 62-64) is not "particulate matter of ... leaves", or "particulate matter of ... an active pharmaceutical".

Therefore, we submit that claim 30 is not anticipated by Short. Should the Examiner disagree with the Applicant, the Examiner should respectfully point out to the Applicant where Short teaches, discloses, or suggests the above recited feature of claim 30.

Claim 30 also recites: "generating pellets of the particulate matter in substantial absence of fillers, diluents or binders;" (Emphasis added)

Short discloses a method to produce "binder-disintegrant pre-compacted starch powder" (Short column 7 line 50), wherein "precompacted starch powder is subjected to physical compaction" (Short column 8, line 1-3). Accordingly, since the product which is compacted in the method disclosed in Short consists of starch which is a binder, Short does not disclose "generating pellets... in absence of fillers diluents or binders"

We therefore submit that claim 30 is not anticipated by Short. Should the Examiner disagree with the Applicant, the Examiner should respectfully point out to the Applicant where Short teaches, discloses, or suggests the above recited feature of claim 30.

Claim 30 further recites "directing particulate matter... in a first powderized form... having a first density... and milling... into a second powderized form... [having] a greater density than the first density". Although Short talks about density at column 8, line 13, the Applicant has not been able to find in Short where "a second powderized form... [having] a greater density than the first density" (Emphasis added).

Therefore, the Applicant submits that claim 30 is not anticipated by Short also because Short does not describe the above recited feature. Should the Examiner disagree with the Applicant, the Examiner should respectfully point out to the Applicant where Short teaches, discloses, or suggests the above recited feature of claim 30. The Applicant respectfully points out to the Examiner that, in accordance with 37 CFR § 104(c)(2) "the pertinence of each reference, if not apparent, must be clearly explained" (emphasis added).

Claim 31 has been canceled. Claims 33, 37, 41, and 42 directly or indirectly depend on claim 30. Therefore, those claims are deemed to be novel over Short at least by virtue of their dependency on claim 30.

4.

Claim 43 recites: "directing a particulate matter into a pellet mill ... the particulate matter selected from the group consisting of particulate matter of whole plants, leaves, roots, dried fruits and active pharmaceuticals..." (Emphasis added).

Therefore, the Applicant submits that claim 43 is novel over Short for the same reasons reported for claim 30 on paragraph 1. above. Should the Examiner disagree with the Applicant, the Examiner should respectfully point out to the Applicant where Short teaches, discloses, or suggests the above recited feature of claim 43.

5.

Claim 43 also recites: "generating pellets of the particulate matter in substantial absence of fillers, diluents or binders;" (Emphasis added)

Therefore, the Applicant submits that claim 43 is novel over Short for the same reasons reported for claim 30 on paragraph 2. above. Should the Examiner disagree with the Applicant, the Examiner should respectfully point out to the Applicant where Short teaches, discloses, or suggests the above recited feature of claim 43.

б.

Claim 43 further recites "directing particulate matter . . . in a first powderized form . . . having a first density . . . and milling . . . into a second powderized form . . . [having] a greater density than the first density" (emphasis added). Therefore, the Applicant submits that claim 43 is novel over Short for the same reasons reported for claim 30 on paragraph 3. above. Should the Examiner disagree with the Applicant, the Examiner should respectfully point out to the Applicant where Short teaches, discloses, or suggests the above recited features of claim 43.

Claim 44 has been canceled. Claims 48 and 52 depend on claim 43. Therefore, those claims are deemed to be novel over Short at least by virtue of their dependency on claim 43.

7.

Claims 55, 57 and 59 are product-by-process claims wherein the process is respectively the process of claim 30, 33 and 41. Applicant submits that Short does not disclose teach or

suggest a milled product obtainable by the processes of claims 30, 33 and 41, at least because of the nature of the particulate matter which forms the milled product of claims 55, 57 and 59 ("whole plants, leaves, roots dried fruits or active pharmaceuticals" which is not "pre-compacted starch powder" (Short column 8, line 1)) and because of the composition of the pellet of claims 55, 57 and 59 which lacks of "fillers diluents or binders".

Therefore, Applicant submits that claims 55, 57 and 59 are not anticipated by Short.

Claim 56 has been canceled, thus rendering moot the rejection of the Examiner.

VII. Claims rejections - 35 USC § 103

8.

In the Action, the Examiner rejects claims 38, 42, 49, 53, 54, 58, 60, and 61 under 35 USC 103(a) as being unpatentable over Short. The Applicant respectfully disagrees.

9.

Claims 38 and 42 depend on claim 30, while claims 49 and 53 depend on claim 43.

Claims 30 and 43 recite: "directing a particulate matter into a pellet mill ... the particulate matter selected from the group consisting of particulate matter of whole plants, leaves, roots, dried fruits and active pharmaceuticals..." (emphasis added).

Claims 30 and 43 also recite: "generating pellets of the particulate matter in substantial absence of fillers, diluents or binders;" (Emphasis added)

Claims 30 and 43 further recite: "a second powderized form . . . [having] <u>a greater</u> <u>density</u> than the first density" (emphasis added) as already stated above.

The Applicant submits that the absence of these features from Short and the absence of an explanation why this feature should be taught or suggested by Short does not put the Examiner in a position to make a *prima facie* rejection of claims 38, 42, 49, and 53 under 35 USC § 103(a). Therefore, the Applicant submits that claims 38 and 42 are patentable over Short. 10.

Claim 54 recites "directing a particulate matter into a pellet mill ... the particulate matter selected from the group consisting of particulate matter of whole plants, leaves, roots, dried fruits and active pharmaceuticals...". Claim 54 also recites: "generating pellets of the particulate matter in absence of fillers, diluents or binders;" (Emphasis added)

Claim 54 further recites "a second powderized form having a second density greater than the first density." Therefore, claim 54 is deemed to be patentable over Short for the same reasons as explained on point 9. above.

11.

Claims 58, 60 and 61 are product-by-process claims wherein the process is respectively the process of claim 38, 42 and 54. Applicant submits that Short does not disclose teach or suggest the milled product obtainable by the processes of claims 38, 42 and 54, at least because of the nature of the particulate matter which forms the milled product of claims 58, 60 and 61 ("whole plants, leaves, roots dried fruits or active pharmaceuticals" which is not "pre-compacted starch powder" (Short column 8, line 1)) and because of the composition of the pellet of claims 58, 60 and 61 which substantially lacks of "fillers diluents or binders".

Therefore, Applicant submits that claims 58, 60 and 61 are deemed to be patentable over Short.

12.

In the Action, the Examiner rejects claims 30, 32-43, 45-53, 55, 57-60 under 35 USC 103(a) as being unpatentable over the admitted prior art (APA) in view of U.S. Pat. No. 5,229,348 to Ivie. The Applicant respectfully disagrees.

Claims 30 and 43 recite "generating pellets of the particulate matter . . . in substantial absence of fillers, diluents or binders." In sharp contrast, APA discloses "preblending with compressible fillers and diluents in order to achieve compaction" (see present application page 1, lines 21-22) or an "alternate way" (see present application page 1, line 29) with "diluents and fillers" (see present application page 2, line 1). Additionally, Ivie discloses a step of "adding an additive" before compacting (see Ivie, step (b) of independent claims 1, 14, and 18). Therefore, the Applicant submits that the combination of APA and Ivie does not put the Examiner into a condition to make a prima facie case of obviousness under § 103(a) against claims 30 and 43.

Claims 32-41 directly or indirectly depend on claim 30. Claims 45-53 directly or indirectly depend on claim 43. Therefore, they are deemed to be patentable over the combination of APA and Ivie at least by virtue of their dependence on claims 30 and 43, respectively.

13.

Claims 55, 57 and 59 are product-by-process claims wherein the process is respectively the process of claim 30, 33 and 41. Applicant submits that APA and Ivie do not disclose, teach or suggest the product obtainable by the processes of claims 30, 33 and 41, at least because of the nature of the particulate matter which forms the milled product of claims 55, 57 and 59 ("whole plants, leaves, roots dried fruits or active pharmaceuticals" which is not "pre-compacted starch powder" (Short column 8, line 1)) and because of the composition of the pellet of claims 55, 57 and 59, which substantially lacks "fillers diluents or binders".

Therefore, claims 55, 57 and 59 are deemed to be patentable over the combination of APA and Ivie.

VII. New claims

14.

New claims 62-80 are enclosed with the present response.

New independent claims 62 and 71 recite "the particulate matter selected from the group consisting of particulate matter of whole plants, leaves, roots, dried fruits and active pharmaceuticals", "generating pellets of the particulate matter in substantial absence of fillers, diluents or binders;" and are deemed to be patentable over the cited art also for the same reasons as provided with reference to claim 30 on point 1 and 2 above.

Additionally claim 62 also recites: "directing particulate matter... in a first powderized form... having a first granularity... and milling... into a second powderized form... [having] a greater granularity than the first granularity" (emphasis added)

Furthermore, claim 71 also recites "directing particulate matter . . . in a first powderized form . . . having a first flowability . . . and milling . . . into a second powderized form . . . [having] a greater flowability than the first flowability" (emphasis added)

Although Short talks about granular material at column 10, line 60, and of flowability at column 11 starting from line 20, the Applicant has not been able to find in Short where "a second powderized form . . . [having] a greater granularity than the first granularity" (emphasis added) or "a second powderized form . . . [having] a greater flowability than the first flowability" (emphasis added) is disclosed.

Attorney Docket No. 58598-010100

15.

New claims 63 and 64 are deemed to be patentable at least by virtue of their dependency on claim 62.

New independent claims 65 and 74 are a product-by-process wherein the product includes "matter of whole plants, leaves, roots, dried fruits [or] pharmaceutical actives", is produced in "substantial absence of fillers diluents or binders" and is deemed to be patentable over the cited prior art at least for the same reasons reported with respect to claim 55, 57 and 59 on point 5. above.

New claims 66 to 72 are deemed to be patentable at least by virtue of their dependency on claim 65. New claims 75 to 80 are deemed to be patentable at least by virtue of their dependency on claim 74.

The Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Should matters remain which the Examiner believes could be resolved in a further telephone interview, the Examiner is requested to telephone the Applicant's undersigned agent.

The Commissioner is hereby authorized to charge any required fee in connection with the submission of this paper, any additional fees which may be required, now or in the future, or credit any overpayment to Account No. 50-2638. Please ensure that the Attorney Docket Number is referred to when charging any payments or credits for this case.

Date: April I, 2004

Charles Berman

Registration No. 29,249

Respectfully submitted

Customer Number 33717 GREENBERG TRAURIG, LLP 2450 Colorado Avenue, Suite 400E Santa Monica, CA 90404

Phone: (310) 586-7703 Fax: (310) 586-0203

E-mail: bermanc@gtlaw.com